DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BIOTEST MEDICAL CORP.
YUHUA CHEN
NO.3-2, CHIEN-KUO ROAD, TEPZ, TANTZU, 427
TAICHUNG, TAIWAN

May 19, 2015

Re: K141351
Trade/Device Name: SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S), SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: May 20, 2014
Received: May 22, 2014

Dear Yuhua Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141351

Device Name
SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M)

Indications for Use *(Describe)*
The SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M) is composed of the SuperCheck Plus Multi Test Strips and SuperCheck Plus Multi Blood Glucose Meter and is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from fingertips or forearm, or in venous whole blood. The SuperCheck Plus Multi Blood Glucose Monitoring System(Model 5228-M) is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancets.

The SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M) should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly).

The SuperCheck Plus Multi Test Strips are for use with the SuperCheck Plus Multi Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from fingertips or forearm, or in venous whole blood.

The SuperCheck Plus Multi Control Solutions are for use with the SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M) as a quality control check to verify that the meter and test strips are working together properly.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141351

Device Name
SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S)

Indications for Use *(Describe)*
The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or forearm. The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) is intended to be used by a single person and should not be shared.
The SuperCheck Plus Blood Glucose Monitoring System(Model 5228-S) is intended for self-testing outside the body(in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program. The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The SuperCheck Plus Test Strips are for use with the SuperCheck Plus Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips or forearm.

The SuperCheck Plus Control Solutions are for use with the SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) as a quality control check to verify that the meter and test strips are working together properly.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(Per 21 CFR 807.92)

1. Submitter Information

Company Name	Biotest Medical Corporation
Address	No. 3-2 , Chien-kuo road, TEPZ Tantzu, 427, Taichung, Taiwan
Contact Person	Yuhua Chen
Phone	886-4-2532-6668
Fax	886-4-2532-6593
Email	yuhuachen@mail.biotestsystems.com
Date Prepared	**May 14, 2015**

2. Device Name

Proprietary Name	SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M)
Common Name	Blood Glucose Test System
Classification Number	System, Test, Blood Glucose, Over the Counter
Classification Panel	Chemistry
Product Code	NBW, LFR, JJX
Regulation Number	862.1345

3. Predicate Device

Proprietary Name	ACCU-CHEK Performa System
Common Name	Blood Glucose Test System
Manufacturer	Roche Diagnostics Corporation
510(k) Number	K070585

4. Device Description

The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) (also applicable to: SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M)) is a product kit consisting of a blood glucose meter, test strips, control solutions, a lancing device, lancets, and instructions for use.

The data download functionality is optionally available and sold separately. To perform a test, when a small drop of blood is applied to the end of the test strip, glucose reacts with the reagents on the test strip, producing an electrical current that is proportional to the blood glucose concentration. The glucose concentration is calculated by the glucose meter and is based on the electrical current measured. The quantitative glucose concentration (in mg/dL or mmol/L) is displayed on the display screen.

5. Intended Use

For single patient use

SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S)

The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or forearm. The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) is intended to be used by a single person and should not be shared.
The SuperCheck Plus Blood Glucose Monitoring System(Model 5228-S) is intended for self-testing outside the body(in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program. The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).
The SuperCheck Plus Test Strips are for use with the SuperCheck Plus Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips or forearm.
The SuperCheck Plus Control Solutions are for use with the SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) as a quality control check to verify that the meter and test strips are working together properly.

For multiple patient use

SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M)

The SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M) is composed of the SuperCheck Plus Multi Test Strips and SuperCheck Plus Multi Blood Glucose Meter and is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from fingertips or forearm, or in venous whole blood. The

SuperCheck Plus Multi Blood Glucose Monitoring System(Model 5228-M) is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancets.

The SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M) should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly).

The SuperCheck Plus Multi Test Strips are for use with the SuperCheck Plus Multi Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from fingertips or forearm, or in venous whole blood.

The SuperCheck Plus Multi Control Solutions are for use with the SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M) as a quality control check to verify that the meter and test strips are working together properly.

6. Comparison to Predicate Device

Similarities		
Item	SuperCheck Plus Blood Glucose Monitoring System(Model 5228-S) SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M) (Proposed devices)	ACCU-CHEK Performa System (Predicate device)
Enzyme	FAD- glucose dehydrogenase	Glucose dehydrogenase with nitrosoaniline mediator
Measurement principle	Same	Amperometric method
Sample type	Same	Fresh capillary whole blood Venous whole blood
Power	Same	Two 1.5V AAA alkaline batteries

Glucose units	Same	Either mg/dL or mmol/L
Strip vial open time	Same	90 days
Test time	Same	5 seconds
Memory	Same	500 measurements with day and time
PC link	Same	Yes
Strip storage condition	2~30℃(35.6-86˚F)/20-80%RH	2~30℃(35.6-86˚F)
Differences		
Weight	72g	62g
Dimensions	100mm(L)x50mm(W)x20mm(H)	93mm(L)x52mm(W)x22mm(H)
Test volume	0.7μL	0.6μL
Test Range	20-600 mg/dL	10-600 mg/dL
Operating condition	10~40℃(50-104˚F) 20~80% RH (non-condensing)	6~44℃(39.2-111.2˚F) 10~90% RH
Alternate site capability	Forearm	Palm, forearm, upper arm, thigh, and calf
Hematocrit range	20-60%	10-70%
Coding	No	Yes (A Code Key is provided with each box of test strips to calibrate the meter for that strip lot.)

7. Non-Clinical Performance Characteristics

A brief description of analytical performance for these studies listed below is included in this submission.

a. Precision/Reproducibility

Precision/Reproducibility evaluations were conducted by performing repeatability precision (within-run precision) and intermediate precision (total precision) based on ISO 15197. Repeatability precision was performed on 5 whole blood concentrations (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL). For glucose concentration was less than 100 mg/dL, the test results of CV values were not more than 7%. For glucose concentration was more than or

equal to 100mg/dL, the test results of CV values were less than 5%.
Intermediate precision was performed on 3 levels of control solutions (30-50mg/dL, 96-144mg/dL and 280-420mg/dL) with 3 lots of test strips and 10 meters for 10 days. The test results of CV values were less than 5%.

b. Linearity/assay reportable range

The linearity study was performed using capillary whole blood samples. The capillary samples were spiked to 11 concentration levels from 20-600 mg/dL. Linear regression showed a correlation of r^2=0.9998 compared to the reference method (YSI analyzer) over the range 21 mg/dL to 592 mg/dL.

The measuring range of the SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring Systems is 20-600 mg/dL.

c. Operating Temperature and Humidity Study

The study confirmed the operation of the SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring System for temperature range of 10-40°C(50-104°F) and the relative humidity range of 20-80%, noncondensing.

d. Analytical specificity

Nine endogenous substances and thirteen exogenous substances were analyzed at two concentrations of glucose and interferent according to NCCLS EP 7. For glucose concentrations is less than 100mg/dL, the average difference between the tested and the control sample is within 10 mg/dL. For glucose concentrations is more than or equal to 100 mg/dL, the average difference between the tested and the control sample is within 10%. Results are presented in the table below:

Interfering substances	Highest concentration at which no interference is observed
Endogenous substances	
Billrubin	20.8 mg/dL
Cholesterol	648.1 mg/dL
Creatinine	5.95 mg/dL
Fructose	30 mg/dL

Galactose	60 mg/dL
Glutathione	23.5 mg/dL
Glyceryl Tributyrate	3039.3 mg/dL
Hemoglobin	20 g/dL
Uric Acid	9.5 mg/dL
Exogenous substances	
Acetaminophen	20 mg/dL
Ascorbic Acid	4.5 mg/dL
Dopamine	1.25 mg/dL
Gentistic acid	6.75 mg/dL
Ibuprofen	50 mg/dL
L-Dopa	1.9 mg/dL
Maltose	1000 mg/dL
Methy Dopa	1.5 mg/dL
Pralidoxime Iodide(PAM)	62.5 mg/dL
Salicylate	115.5 mg/dL
Tolazamide	3.8 mg/dL
Tolbutamide	64 mg/dL
Xylose	6.3 mg/dL

The accuracy study of EDTA anticoagulated whole blood samples used with SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring System compared to results obtained using a capillary sample collected in heparin with a reference method (YSI glucose analyzer) were evaluated. The result of the study was shown that SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring System produce accurate glucose results when the blood samples are collected in EDTA tube.

e. Hematocrit Study

Nine hematocrit levels of 20, 25, 30, 35, 42, 45, 50, 55 and 60% at 3 spiked target glucose concentrations were evaluated. The study showed no significant hematocrit effect from 20%-60% for samples with concentration levels over dynamic range (20-600 mg/dL).

f. Altitude Study

Venous blood samples were spiked to 3 glucose concentration (30-50 mg/dL, 96-144 mg/dL, 280-420 mg/dL). The samples were performed at 33 ft and 10,744 ft. Values were compared to the YSI 2300 (reference

method). The results demonstrated that altitudes up to 10,744 ft have no significant effect on blood glucose measurement from the SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring Systems.

g. Sample volume study

The blood volume test was performed from 0.5µl to 3.0ul by using the blood samples spiked to produce 3 glucose concentrations (30-50 mg/dL, 96-144 mg/dL, 280-420 mg/dL) for verifying the performance of test strip.

The results showed that error message was displayed for insufficient sample volume of 0.7ul; therefore the SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring Systems claim that sample volume of ≥0.7ul produces accurate blood glucose results.

h. Meter reliability study

The reliability test was performed before and after challenge including mechanical resistance to drop and vibration and protection against exposure to temperature and humidity levels. All results were within the criteria. It demonstrates that SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) meters produced accurate results within its claimed temperature and humidity limits.

i. EMC and electrical safety study

SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring Systems by performing Electromagnetic Interference and Safety Test to verify the product conform IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1 and IEC/EN 61326-2-6 standards. All the results revealed the system was complied with the above related standards.

j. Infection control studies

The systems are intended for single-patient use (SuperCheck Plus (5228-S)) and multiple-patient use (SuperCheck Plus Multi (5228-M)).

Cleaning and disinfection can be accomplished by wiping the meter with Clorox® Germicidal Wipes (EPA Reg. No. 67619-12). The robustness study was conducted and the results demonstrated that there was no

change in performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles to simulate 3 years of use for multiple-patient use and after 5475 cleaning cycle and 156 disinfection cycles to simulate 3 years of use for single-patient use.

Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B (HBV) with chosen disinfectant, HEALTHCARETM Bleach Germicidal Wipes by the Clorox Company (EPA registered # 67619-12).

8. Clinical Performance Characteristics

a. System Accuracy Study

The accuracy study of SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring Systems was compared to YSI 2300 (reference method). A total of 151 subjects were recruited. The study result demonstrates that the accuracy of SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring Systems met the acceptance criteria.

b. User Performance Study

The study was performed with 129 participants to demonstrate the accuracy of the SuperCheck Plus (Model 5228-S) Blood Glucose Monitoring System. Participants, who were able to read the User's Manual in English, were instructed to read the manual and perform testing on the finger and the forearm. The study results met the acceptance criteria and according to the results of questionnaire, SuperCheck Plus (5228-S) and SuperCheck Plus Multi (5228-M) Blood Glucose Monitoring Systems are easy to use for participants.

9. Conclusion

Laboratory testing and clinical testing results of SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) and SuperCheck Plus Multi Blood Glucose Monitoring System (Model 5228-M) demonstrated satisfactory and support their Indications for Use. It also demonstrates that SuperCheck Plus (Model 5228-S) and SuperCheck Plus Multi (Model 5228-M) are substantial equivalence to the predicate.